EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

Hon. F. Kay Behm

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names, and; ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

DECLARATION OF CHAD COSTLEY, MD, MBA IN SUPPORT OF BLUEWILLOW BIOLOGICS, INC.'S REPLY BRIEF REGARDING MOOTNESS OF CASE

I, Chad Costley, MD, MBA, declare as follows:

1. I am President and Chief Executive Officer of BlueWillow Biologics, Inc. I have personal knowledge of the facts set forth below, and if called upon to do so, I could and would testify thereto.

2. BlueWillow Biologics, Inc. is a biotechnology company focused on developing intranasal vaccine candidates. Prior to serving as President and Chief Executive Officer of BlueWillow Biologics, Inc. I received a medical degree from the University of Michigan. I have been engaged in the clinical practice of medicine for over 20 years.

CDC

3. Vaccines can be developed using various technologies such as mRNA (e.g., Moderna's Covid-19 vaccine), weakened live viruses (e.g., Astra-Zeneca's intranasal FluMist) or as is the case for BlueWillow's vaccine candidates, combining a small portion of a pathogen (an "antigen") with a delivery system that also stimulates the immune system (an "adjuvant"). Regardless of the technology utilized, all vaccines work by causing the immune system to be prepared to fight an infection caused by a pathogen that arrives weeks, months or years after the vaccine was administered. In other words, vaccines only trigger an immune response in the body to fight a later infection; vaccines do not kill, inactivate, or disable pathogens at the time vaccines are administered to patients.

4. The vaccine development process is lengthy, usually taking more than a decade to complete before any vaccine can be commercialized. For example, the recently approved mRNA vaccines for Covid-19 resulted from decades of developmental work that began in the 1990s. In order to commercialize a vaccine in the United States, companies must undergo a lengthy process regulated by the U.S. Food and Drug Administration ("FDA"). The process starts with a research and discovery phase in the laboratory, moving next to pre-clinical testing in animals, followed by several stages of clinical testing in humans. The human clinical testing stage itself has three phases – Phase I

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(testing in small groups for safety and indications of the type of immune response elicited), Phase II (testing in slightly larger groups for safety and efficacy), followed by Phase III (testing in large groups to prove safety and efficacy). At each stage, the data is assessed to determine whether the vaccine candidate shows enough promise to move to the next stage. After successful completion of all of these stages, the vaccine sponsor files a Biological License Application to the FDA, which reviews the pre-clinical and clinical data to determine if the vaccine should be approved for human use in the United States. Given the lengthy process and the numerous stages at which a vaccine candidate can fail to progress, most vaccine candidates are never commercialized.

5. BlueWillow's vaccine candidates are in the early stages of the overall development process, ether in pre-clinical or clinical Phase I testing. BlueWillow has completed only two Phase I trials, and neither of those vaccine candidates have advanced to Phase II trials despite the Phase I trials being completed. Nor have any of the vaccine candidates entered Phase III testing. Therefore, BlueWillow has not yet prepared and/or submitted any application to FDA for approval and is many years away from potentially being in a position to do so.

6. Based on the current development status, BlueWillow does not expect any of its developmental vaccine candidates to receive FDA approval and

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be commercialized in the U.S. for more than five years.

7. The nanoemulsion adjuvant in BlueWillow's vaccine candidates is not the same as the formulation in NanoBio® Protect in that it includes different ingredients and different concentrations of ingredients.

8. BlueWillow will not sell NanoBio® Protect at any time in the future and is willing to execute and file a stipulation with the Court confirming this fact.

9. I declare under penalty of perjury that the foregoing is true and correct and that this Declaration was executed this 12th day of January, 2024.

Chad Costley, MD, MBA